The Atlantic

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Cardiovascular Patient Outcomes Research Team

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Rex W. Cowdry, M.D.
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Dr. Cowdry:

This letter is submitted in response to the request for public comment regarding the draft regulations concerning Title 10, subtitle 24, Chapter 5, "Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery". Comments will fillow the outline of the Draft for Informal Public Comment, dated May 10, 2007 and available as a pdf file at the Commission website.

B. Eligibility to File Application:
1. I am concerned that no hospitals in the Metropolitan Baltimore of Metropolitan Washington regional service areas currently (as of May 15, 2007) have a 2-year primary PCI waiver. This would appear to create a circumstance in which while the study is approved, the regulations governing participation make that approval irrelevant. I realize that the process of renewing waivers for primary PCI programs will occur in June and July of 2007, so that it is possible that at least some facilities in these two regions where all of the current primary PCI programs reside may be able to apply if their renewal is for 2 years.

2. I do not think that the 6 month (or 18 primary PCI completion) period for hospitals on the Eastern Shore or Western Maryland regional service areas is reasonable. First, there is debate about which programs (elective or primary) should begin first at a hospital without surgery on-site. For example, the Mayo Clinic group strongly believes a period of elective PCI should precede performance of primary PCI. Others feel the opposite. In C-PORT E, we have left it up to the local interventionalists. Most begin primary and elective simultaneously; and others begin with elective for 3 or 4 months and then begin primary PCI. Both are common. My strong feeling is to have potential participating site (1) have 24/7 coverage from the start (which is required even for elective PCI) but (2) allow them to either simultaneously or sequentially begin elective and primary PCI (with the limitation that primary PCI begin within 3 or 4 months of beginning elective PCI).

The second reason this Eligibility to File (2) is not reasonable is that these rural hospitals in the Eastern Shore and Western Maryland regions are in a "catch-22" situation: they cannot get interventionalists for primary-PCI-only coverage unless they can also offer elective PCI. Your

requirement means they cannot even apply for elective PCI unless they already have primary PCI up and running. And the cycle continues. I realize fully (as do the sites) that this is a research study that will terminate after a certain period. However, their ability to recruit the best interverntionalists will be increased substantially by being able to tell them that at least for this period elective PCI will definitely be available – rather than possibly available after we start up primary PCI and do that for at least 6 months.

Regarding .04 Review of Applications, I have the following observations and suggestions regarding part A Review Criteria.

(2)(a)(i-iii). These should already be in place in some form for all sites currently performing primary PCI. So it might be reasonable to simply request that the mechanisms and agreements currently in place be extended to include elective PCI patients.

2(e) This section does not exist, but I would request that it be added. The facilities must demonstrate and commit to performance of research. This effort is significantly more time consuming and requires much greater effort than the current MHCC primary PCI registry. The personnel currently allocated at each site in Maryland is far, far below what will be required for this project. There will be, at a minimum, a requirement of 1 FTE at the RN level as the primary coordinator *plus* additional backup and help at the RN level. How much additional will depend upon the volume. The institutions must state up front that they recognize this and will fulfill whatever the institution needs in terms of research-specific personnel.

3(c) I would restate this as "An applicant's ability and commitment to serve as a site for conducting research;"

Regarding .06 Conditions for Maintaining as Waiver:

3. The outcomes the IRB's in CPORT require an immediate notice for are only death and coronary artery bypass surgery required because of a complication of PCI. The reports are due within 3 *working* days of the *discovery* of the event. I would not include MI or stroke.

I will say that as a general rule, no states require 200 PCI's in the first year (eg. neither Georgia nor New Jersey require that). The reason is that it sometimes takes some time for a study to 'ramp up'. It might be reasonable to modify this in some way to account for the ramp-up phenomenon. One way is to select a lower number for the first year and 200 for the second – that is what both Georgia and New Jersey did.

As always, my thanks to you and the Commissioners for moving forward with this important project.

Sincerely yours,

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